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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,630	04/09/2004	Jill E. Parker	AFD 503	5340

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DEPARTMENT OF THE AIR FORCE
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WRIGHT-PATTERSON AFB, OH 45433-7109

EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,630	PARKER ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *5-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 4* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed June 28, 2005 has been received and entered. New claims 2-10 have been added. Accordingly, claims 1-10 are pending in the instant application.

Election/Restrictions

Newly submitted claims 5-10 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 5, drawn to a composition of medium nutrients is distinct from the elected strain of Bacillus, since Bacillus is a distinct microorganism capable of independent replication and growth.

Claims 6-9, drawn to methods comprising inoculating a bacteria strain in the growth medium is distinct from the elected strain of Bacillus, since Bacillus is a distinct microorganism capable of independent replication and growth.

Claim 10, drawn to methods for the expression of proteins is distinct from the elected strain of Bacillus, since Bacillus is a distinct microorganism capable of independent replication and growth.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 5-10 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

1. The objection of claim 1 for failing to end with the punctuation mark of a period is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

2. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure without complete evidence that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of biological materials is withdrawn in view of Applicants response.

3. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic strains, does not reasonably provide enablement for vaccine strains is maintained.

Applicants are asserting that the Office Actions insistence on prevention is an improper insistence on enabling a perfected, commercially viable embodiment. Applicants argue that claim 1 should be read in light of the specification which sets forth that "a vaccine strain of Bacillus anthracis ***from which may be produced*** an improved anthrax vaccine." (Emphasis added). Applicants further assert that Simonson (US Pub 2003 0143636) is not relevant to the language of rejected claim 1, since the Simonson reference does not contain the phrase "vaccine strain."

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the Office Actions insistence on prevention is an improper

insistence on enabling a perfected, commercially viable embodiment, Applicants argue that claim 1 should be read in light of the specification which sets forth that "a vaccine strain of Bacillus anthracis ***from which may be produced*** an improved anthrax vaccine." However, it is precisely the claim language of "vaccine" which requires a reasonable degree of protection to be deemed enabled. A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Furthermore, Example 9 of the specification demonstrates a lethality study comparing the Alls/Gifford strain of the invention with the Sterne strain and shows the results in Figure 5. While Applicants note a time to death to be prolonged following infection with the Alls/Gifford strain, Applicants will appreciate that the ultimate percent survival in both cases was zero percent. Simply stated, a zero percent survival is not commensurate in scope with claim language reciting a "vaccine."

Finally, Applicants assert that Simonson (US Pub 2003 0143636) is not relevant to the language of rejected claim 1, since the Simonson reference does not contain the phrase "vaccine strain." However, as set forth previously Simonson set forth "***vaccine efficacy*** in one animal model cannot be compared to the protection afforded other animals ***immunized with the same vaccines*** or challenged with the same anthrax strains. This also clearly points out the inherent difficulty in extrapolating results of anthrax ***vaccine protection*** in animals to that in patients." (Emphasis added). Challenge strains are only administered after the host has been vaccinated with the "vaccine strain" to determine the protectiveness of the vaccine.

Facts that should be considered in determining whether a specification is enabling, or if it

would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

First, US Publication (2003/0143636) sets forth that in dealing with anthrax vaccination "vaccine efficacy in one animal model cannot be compared to the protection afforded other animal immunized with the same vaccines or challenged with the same anthrax strains. This also clearly points out the inherent difficulty in extrapolating results of anthrax vaccine protection in animals to that in patients." This teaching directly addresses factors 1, 4, 5, 6, 7 and 8.

Second, Applicants specification provides no working examples demonstrating prevention with the strain of the invention. To the contrary, Example 9 of the specification demonstrates a lethality study comparing the Alls/Gifford strain of the invention with the Sterne strain and shows the results in Figure 5. While Applicants note a time to death to be prolonged following infection with the Alls/Gifford strain, Applicants will appreciate that the ultimate percent survival in both cases was zero percent. This directly affects Factors 1, 2, 3, 4 and 8.

A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27

USPQ2d 1510, 1513 (Fed. Cir. 1993).

Given the lack of guidance, lack of working examples, and the unpredictable nature of the invention, one of skill in the art would be forced into excessive experimentation in order to practice the instantly claimed invention.

For reasons of record as well as those set forth above, this rejection is maintained.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivins et al.

The claims are directed to a mutated strain of Bacillus anthracis having: presence of pX01 plasmid, synthesis of Diazoluminomelanin, sensitivity to Penicillin, ability to be lysed by Cherry gamma phage, non-hemolytic, production of nitrite from nitrate, and thermal resistance up to about 240 degrees Celsius.

Ivins et al (US Patent Number 6,387,665) disclose of spore forming strain B. anthracis ΔSterne-1(pPA102). (See column 8).

It is noted that Applicants specification, page 12, sets forth that Sterne strains, contain the pX01 plasmid, produce diazoluminomelanin, sensitivity to Penicillin, ability to be lysed by Cherry gamma phage, non-hemolytic, and produce nitrite from nitrate. It is further noted that Figure 2 of the instant application shows the thermal resistance of both the Sterne strain and the Alls/Gifford strain of the instant invention. While the CFU of the Sterne strain do show a decrease at about 240 degrees, it does not drop to zero. Given that the claim does not set forth what amount of thermal resistance must be present, the survival of even a single strain at about 240 degrees is deemed to meet the limitation of "thermal resistance up to about 240 degrees."

Furthermore, since there are multiple Sterne strains of Bacillus anthracis and claim 4 does not recite which particular strain is being compared, strain B. anthracis ΔSterne-1(pPA102) is deemed to be able to delay the onset of death relative to other Sterne strains.

Accordingly, Ivins et al disclose of each and every limitation of the claimed mutated strain.

5. Claims 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Keim et al.

The claims are directed to a mutated strain of Bacillus anthracis having: presence of pX01 plasmid, synthesis of Diazoluminomelanin, sensitivity to Penicillin,

ability to be lysed by Cherry gamma phage, non-hemolytic, production of nitrite from nitrate, and thermal resistance up to about 240 degrees Celsius.

Keim et al (US Publication 2002/0055628) disclose of vaccine strains, Sterne STI-1 and V770-NP1. (See paragraph 36).

It is noted that Applicants specification, page 12, sets forth that Sterne strains, contain the pX01 plasmid, produce diazoluminomelanin, sensitivity to Penicillin, ability to be lysed by Cherry gamma phage, non-hemolytic, and produce nitrite from nitrate. It is further noted that Figure 2 of the instant application shows the thermal resistance of both the Sterne strain and the Alls/Gifford strain of the instant invention. While the CFU of the Sterne strain do show a decrease at about 240 degrees, it does not drop to zero. Given that the claim does not set forth what amount of thermal resistance must be present, the survival of even a single strain at about 240 degrees is deemed to meet the limitation of "thermal resistance up to about 240 degrees."

Furthermore, since there are multiple Sterne strains of Bacillus anthracis and claim 4 does not recite which particular strain is being compared, strain Sterne STI-1 and V770-NP1 are deemed to be able to delay the onset of death relative to other Sterne strains.

Accordingly, Keim et al disclose of each and every limitation of the claimed mutated strain.

6. Applicant is advised that should claim 1 be found allowable, claim 2 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Both claims 1 and 2, despite being called a vaccine strain or a mutated strain, are drawn to the identical strain ATCC PTA-3162.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
September 28, 2005